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| FORM PTO-1390 (Modified) U.S. PATENT AND TRADEMARK OFFICE; U.S. DEPARTMENT OF COMMERCE   |  | ATTORNEY'S DOCKET NUMBER<br><b>291326US0PCT</b>                     |
| <b>TRANSMITTAL LETTER TO THE UNITED STATES</b>   |  | U.S. APPLICATION NO. (If known, see 37 CFR 1.5)<br><b>10/579765</b> |
| <b>DESIGNATED/ELECTED OFFICE (DO/EO/US)</b>  |  |   |
| <b>CONCERNING A SUBMISSION UNDER 35 U.S.C. 371</b>   |  |   |
| INTERNATIONAL APPLICATION NO.<br><b>PCT/JP04/17196</b>   | INTERNATIONAL FILING DATE<br><b>18 November 2004</b> | PRIORITY DATE CLAIMED<br><b>19 November 2003</b>                    |
| <b>TITLE OF INVENTION</b><br><b>METHOD OF DETERMINING SUBSTRATE CONTAINED IN HEMOGLOBIN-CONTAINING SAMPLE</b>  |  |   |
| <b>APPLICANT(S) FOR DO/EO/US</b><br><b>Yuriko TANIGUCHI, et al.</b>  |  |   |
| Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:  |  |   |
| <ol style="list-style-type: none"> <li>1. <input checked="" type="checkbox"/> This is a <b>FIRST</b> submission of items concerning a submission under 35 U.S.C. 371.</li> <li>2. <input type="checkbox"/> This is a <b>SECOND</b> or <b>SUBSEQUENT</b> submission of items concerning a submission under 35 U.S.C. 371.</li> <li>3. <input checked="" type="checkbox"/> This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (24) indicated below.</li> <li>4. <input type="checkbox"/> The US has been elected (Article 31).</li> <li>5. <input checked="" type="checkbox"/> A copy of the International Application as filed (35 U.S.C. 371(c)(2))               <ol style="list-style-type: none"> <li>a. <input type="checkbox"/> is attached hereto (required only if not communicated by the International Bureau).</li> <li>b. <input checked="" type="checkbox"/> has been communicated by the International Bureau.</li> <li>c. <input type="checkbox"/> is not required, as the application was filed in the United States Receiving Office (RO/US).</li> </ol> </li> <li>6. <input checked="" type="checkbox"/> An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).               <ol style="list-style-type: none"> <li>a. <input checked="" type="checkbox"/> is attached hereto.</li> <li>b. <input type="checkbox"/> has been previously submitted under 35 U.S.C. 154(d)(4).</li> </ol> </li> <li>7. <input checked="" type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))               <ol style="list-style-type: none"> <li>a. <input type="checkbox"/> are attached hereto (required only if not communicated by the International Bureau).</li> <li>b. <input type="checkbox"/> have been communicated by the International Bureau.</li> <li>c. <input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired.</li> <li>d. <input checked="" type="checkbox"/> have not been made and will not be made.</li> </ol> </li> <li>8. <input type="checkbox"/> An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).</li> <li>9. <input checked="" type="checkbox"/> An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).               <ol style="list-style-type: none"> <li>a. <input type="checkbox"/> If the declaration is in a language other than the English language, it is accompanied by an English translation. The translation is accurate (37 CFR 1.69)</li> </ol> </li> <li>10. <input type="checkbox"/> An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371 (c)(5)).</li> <li>11. <input type="checkbox"/> A copy of the International Preliminary Examination Report (PCT/IPEA/409).</li> <li>12. <input checked="" type="checkbox"/> A copy of the International Search Report (PCT/ISA/210).</li> </ol> <p style="margin-left: 20px;"><b>Items 13 to 23 below concern document(s) or information included:</b></p> <ol style="list-style-type: none"> <li>13. <input checked="" type="checkbox"/> An Information Disclosure Statement under 37 CFR 1.97 and 1.98.               <ol style="list-style-type: none"> <li>a. <input checked="" type="checkbox"/> PTO-1449    b. <input checked="" type="checkbox"/> Cited References (10)    c. <input type="checkbox"/> Statement of Relevancy    d. <input type="checkbox"/> List of Related Cases.</li> </ol> </li> <li>14. <input type="checkbox"/> An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.</li> <li>15. <input type="checkbox"/> A <b>FIRST</b> preliminary amendment.</li> <li>16. <input type="checkbox"/> A <b>SECOND</b> or <b>SUBSEQUENT</b> preliminary amendment.</li> <li>17. <input checked="" type="checkbox"/> An Application Data Sheet under 37 CFR 1.76.</li> <li>18. <input type="checkbox"/> A substitute specification.</li> <li>19. <input type="checkbox"/> A power of attorney and/or change of address letter.</li> <li>20. <input type="checkbox"/> A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821 - 1.825.</li> <li>21. <input type="checkbox"/> A second copy of the published International Application under 35 U.S.C. 154(d)(4).</li> <li>22. <input type="checkbox"/> A second copy of the English language translation of the International Application under 35 U.S.C. 154(d)(4).</li> <li>23. <input checked="" type="checkbox"/> Other items or information: Notice of Priority/Form PCT/IB/304</li> </ol> <p style="margin-left: 20px;">General Power of Attorney by Assignee (with Statement Under 37 CFR 3.73(b) and attached copy of the Assignment)</p> |  |   |

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| U.S. APPLICATION NO. (If known, see 37 CFR 1.5)<br><b>10/579765</b>   |              | INTERNATIONAL APPLICATION NO.<br>PCT/JP04/17196                        |   | ATTORNEY'S DOCKET NUMBER<br>291326US0PCT |    |
| The following fees are submitted:   |              |  |   | <b>CALCULATIONS</b>                      |    |
|   |              |  |   | <b>PTO USE ONLY</b>                      |    |
| 24. <input checked="" type="checkbox"/> Basic national fee..... \$300   |              |  |   | \$300.00                                 |    |
| 25. <input checked="" type="checkbox"/> Examination fee<br>If the written opinion prepared by ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4) .... \$0<br>All other situations..... \$200   |              |  |   | \$200.00                                 |    |
| 26. <input checked="" type="checkbox"/> Search fee<br>If the written opinion of the ISA/US or the International preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4)..... \$0<br>Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority..... \$100<br>International Search Report prepared by an ISA other than the US and provided to the Office or previously communicated to the US by the IB ..... \$400<br>All other situations..... \$500 |              |  |   | \$400.00                                 |    |
| <b>TOTAL OF 24, 25 AND 26 =</b>   |              |  |   | \$900.00                                 |    |
| <input type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing or computer program listing filed in an electronic medium). The fee is \$250 for each additional 50 sheets of paper or fraction thereof.  |              |  |   |  |    |
| Total Sheets  | Extra Sheets | Number of each additional 50 or fraction thereof (round up to a whole) | RATE  |  |    |
| - 100 =   | 0 / 50 =     | 0  | x \$250.00  | \$0.00                                   |    |
| <input type="checkbox"/> Surcharge of \$130.00 for furnishing any of the search fee, examination fee, or the oath or declaration after the date of commencement of the national stage (37 CFR 1.492(h)).  |              |  |   | \$0.00                                   |    |
| CLAIMS  | NUMBER FILED | NUMBER EXTRA   | RATE  |  |    |
| Total claims  | 21 - 20 =    | 1  | x \$50.00   | \$50.00                                  |    |
| Independent claims  | 7 - 3 =      | 4  | x \$200.00  | \$800.00                                 |    |
| MULTIPLE DEPENDENT CLAIMS (if applicable) <input checked="" type="checkbox"/> + \$360.00  |              |  |   | \$360.00                                 |    |
| <b>TOTAL OF ABOVE CALCULATIONS =</b>  |              |  |   | \$2,110.00                               |    |
| <input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by 1/2.  |              |  |   |  |    |
| <b>SUBTOTAL =</b>   |              |  |   | \$2,110.00                               |    |
| <input type="checkbox"/> Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(i)). +  |              |  |   | \$                                       |    |
| <b>TOTAL NATIONAL FEE =</b>   |              |  |   | \$2,110.00                               |    |
| <input type="checkbox"/> Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property +   |              |  |   | \$                                       |    |
| <input type="checkbox"/> Petition fee of \$1,500.00 for Petition to Revive (37 CFR 1.137 (b)). +  |              |  |   | \$                                       |    |
| <b>TOTAL FEES ENCLOSED =</b>  |              |  |   | \$2,110.00                               |    |
|   |              |  |   | Amount to be refunded:                   | \$ |
|   |              |  |   | Amount to be charged:                    | \$ |
| a. <input type="checkbox"/> A check in the amount of \$_____ to cover the above fees is enclosed.   |              |  |   |  |    |
| b. <input type="checkbox"/> Please charge my Deposit Account No. <u>15-0030</u> in the amount of \$_____ to cover the above fees.   |              |  |   |  |    |
| c. <input checked="" type="checkbox"/> The Director is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. <u>15-0030</u> . A duplicate copy of this sheet is enclosed.   |              |  |   |  |    |
| d. <input checked="" type="checkbox"/> Fees are to be charged to a credit card. <b>WARNING:</b> Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.   |              |  |   |  |    |
| <b>NOTE:</b> Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status.   |              |  |   |  |    |
| SEND ALL CORRESPONDENCE TO:   |              |  |   |  |    |
| CUSTOMER NUMBER<br><b>22850</b>   |              |  | SIGNATURE<br> |  |    |
| Tel. (703) 413-3000<br>Fax. (703) 413-2220<br>(OSMMN 1/06)  |              |  | NAME<br><b>Norman F. Oblon</b> <b>Corwin P. Umbach, Ph.D.</b><br><b>Registration No. 40,211</b>   |  |    |
|   |              |  | REGISTRATION NUMBER<br><b>24,618</b>  |  |    |